K033826

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Summary of Safety and Effectiveness
for the
Orthopedic Alliance Spine System

This safety and effectiveness summary for the Orthopedic Alliance Spine System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

JUL 0 1 2004

1. Submitter :

Orthopedic Alliance LLC
41558 Eastman Drive
Suite A
Marietta, CA 92562

Contact Person :

Roger Williams
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Suite A
Marietta, CA 92562
Telephone: (909) 304-9001

Date Prepared: December 2, 2003

2. Tradename: Orthopedic Alliance Spine System
Common Name: Spinal Fixation System
Classification Name: Pedicle Screw Spinal System (888.3070)

3. Predicate or legally marketed devices which are substantially equivalent :

- Xia Spinal System (Stryker Howmedica)
- Global Spinal Fixation System (U & I Corp.)
- Synergy Spine System (Interpore Cross)

4. Description of the device :

The Orthopedic Alliance Spine System is a top-loading multiple component posterior spinal fixation system which consists of fixed and swivel-head pedicle screws, rods, locking cap screws, and a transverse linking mechanism. The screws are available in various lengths and diameters. The swivel-head pedicle screws are assembled at the factory to provide variable axis screw assemblies. The rods are 4mm in diameter and available in various lengths. The locking cap nuts are applied to the screws after the rods are placed to lock them into position. Cross linkage braces are also available to connect from one rod to another in bilateral constructs.

Materials: The devices are manufactured from CP Titanium and Ti6Al-4V ELI Titanium alloy per ASTM and ISO standards.

Function: The Orthopedic Alliance Spine System functions to provide immobilization and stabilization of the spine as an adjunct to fusion in the treatment of chronic instabilities or deformities of the spine.

5. Intended Use:

The Orthopedic Alliance Spine System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

The Orthopedic Alliance Spine System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

There are no significant differences between the Orthopedic Alliance Spine System and other spinal fixation systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, materials and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 01 2004

Roger Williams
Orthopedic Alliance LLC
41558 Eastman Drive, Suite A
Marietta, California 92562

Re: K033826
Trade/Device Name: Orthopedic Alliance Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI
Dated: May 1, 2004
Received: May 3, 2004

Dear Mr. Williams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) : K033826

Device Name : Orthopedic Alliance Spine System

Indications For Use :

The Orthopedic Alliance Spine System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use X
(PER 21 CFR 801.109)

OR

Over-the-counter use _____

(optional format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033826